

IN RE:

U.S. Patent No. 4,916,246

ISSUED:

April 10, 1990

TO:

Ernst Felder, et al.

FOR:

Paramagnetic Chelates Useful for

NMR Imaging

FROM:

Serial No. 002,115

FILED:

January 12, 1987

Mail Stop Patent Ext.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION ACCOMPANYING APPLICATION OF BRACCO INTERNATIONAL B.V. FOR EXTENSION OF PATENT TERM OF U.S. PATENT No. 4,916,246 UNDER 35 U.S.C. § 156

Sir:

I, GREGORY J. GLOVER, declare as follows:

- I am a patent attorney. I am a member of the District of Columbia bar and am authorized to practice before the U.S. Patent and Trademark Office, Registration No. 34,173.
- I am a partner of Ropes & Gray LLP, One Metro Center, 700 12th Street,
 NW, Suite 900, Washington, DC 20005. I have general authority from BRACCO

INTERNATIONAL B.V. ("BRACCO INT'L") to execute and deliver documents and to otherwise act on its behalf in patent matters.

- 3. BRACCO INT'L is the owner of record of United States Patent No. 4,916,246.
- 4. I have reviewed and I understand the contents of the application of BRACCO INT'L, dated January 21, 2005, which is being submitted herewith for extension of the term of United States Patent No. 4,916,246 under 35 U.S.C. § 156 and 37 C.F.R. § 1.730.
- 5. I believe that United States Patent No. 4,916,246 is subject to an extension pursuant to 37 C.F.R. § 1.710.
- 6. I believe that the length of extension of term of United States Patent No. 4,916,246 of 5 years that is being claimed by BRACCO INT'L is justified under 35 U.S.C. § 156 and the application regulations.
- 7. I believe that the patent for which extension is being sought meets the conditions for extension of the term of a patent as set forth in 35 U.S.C. § 156 and 37 C.F.R. § 1.720.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United

States Code and that such willful false statements may jeopardize the validity of the application being submitted herewith or any extension of patent term granted thereon.

Signed this 21st of January, 2005 at Washington, D.C.

Registration No.





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POWER OF ATTORNEY BY ASSIGNEE

Sir:

Under the provisions of 37 C.F.R. § 3.71, the undersigned assignee of record, by virtue of assignments recorded in the United States Patent and Trademark Office on the 12th day of January 1987 at Reel 4664, Frame 0166, on the 15th day of October 1993 at Reel 6728, Frame 0683 and at Reel 6728, Frame 0685, and on the 7th day of December 1993 at Reel 6790, Frame 0730, of the above-identified patent, hereby elects to conduct the prosecution of the above-identified patent to the exclusion of the inventor. The assignee hereby revokes any powers of attorney previously granted and appoints the attorneys and agents associated with

Customer No. 28120, with power of substitution, to prosecute this patent, and to transact all business in the Patent and Trademark Office connected therewith;

and assignee requests that communications be sent to:

Customer No. 28120 ROPES & GRAY LLP One International Place Boston, MA 02110-2624

and that telephone calls be directed to

Gregory J. Glover (202) 508-4600.

The undersigned hereby certifies that the evidentiary documents have been reviewed and, to the best of the undersigned's knowledge and belief, title is in assignce.

The undersigned hereby declares that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

BRACCO INTERNATIONAL B.V.

Date: ANUARY 20 2005

By Bracco Holding BV
Diana Bracco

Chairman



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OFFICE OF PETITIONS

CONSENT OF BRACCO DIAGNOSTICS INC.

Sir:

Whereas Bracco Diagnostics Inc. and Bracco International B.V. are both indirect subsidiaries of Bracco S.p.A and all are members of the group of companies known as Bracco;

Whereas Bracco Diagnostics Inc. is the owner of New Drug Applications ("NDAs") Nos. 21-357 and 21-358 for MULTIHANCE[®] (gadobenate dimeglumine) and Bracco Diagnostics Inc. acted as agent for Bracco S.p.A. and Bracco International B.V. in obtaining approval of NDAs Nos. 21-357 and 21-358;

Whereas MULTIHANCE® (gadobenate dimeglumine) is claimed in Letters

Patent of the United States No. 4,916,246, and Bracco International B.V. is the legal owner of said Letters Patent by virtue of Assignments, recorded in the United States Patent and

Trademark Office on the 12th day of January 1987 at Reel 4664, Frame 0166, on the 15th day of October 1993 at Reel 6728, Frame 0683 and at Reel 6728, Frame 0685, and on the 7th day of December 1993 at Reel 6790, Frame 0730; and

Whereas Bracco Diagnostics Inc. desires that Bracco International B.V. be able to rely on the marketing approval for MULTIHANCE® (gadobenate dimeglumine) arising from NDAs Nos. 21-357 and 21-358 in Bracco Diagnostics Inc.'s application for extension of the term of U.S. Patent No. 4,916,246 under 35 U.S.C. § 156;

NOW, THEREFORE, Bracco Diagnostics Inc. hereby confirms that it consents and agrees that Bracco International B.V. is fully entitled to rely on said marketing approval for MULTIHANCE® (gadobenate dimeglumine) arising from NDAs Nos. 21-357 and 21-358 in

Bracco International B.V.'s application for extension of the term of U.S. Patent No. 4,916,246 under 35 U.S.C. § 156.

Signed and witnessed this 19 of January, 2005.

BRACCO DIAGNOSTICS INC.

By:

Michael Von Ohlen Associate Corporate Counsel

In the presence of:

Kathleen Lynch-Drummond Manager Legal Affairs



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TRANSMITTAL LETTER FOR APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. § 156

Sir:

Transmitted herewith is the application of BRACCO INTERNATIONAL B.V. for extension of the term United States Patent No. 4,916,246 under 35 U.S.C. § 156, together with a duplicate of the papers thereof, certified as such.

Please charge Deposit Account No. 18-1945 the amount of \$ 1,120.00. The Commissioner is hereby also asked to charge any additional fees which may be required, or

credit any overpayment, to Deposit Account No. 18-1945. Two duplicates of this paper are enclosed.

Date: January 21, 2005

Gregory J. Glover

Reg. No. 34,173/

ROPES & GRAY LLP

Respectfully submitted,

Customer No. 28120

One International Place

Boston, MA 02110-2624

Tel.: 202-508-4600

Fax: 202-508-4650 Attorney for Applicants